Appln. Serial No. 10/665,431 Filed: September 22, 2003

Docket No.: 8932-807-999 CAM No.: 232200-999211

#### **REMARKS**

This amendment is submitted in response to the non-final Office Action mailed December 27, 2005. Following entry of this amendment, claims 1-54 remain pending in the application. In the Office Action, the Examiner:

- rejected pending claims 1, 5, 10-11, 15, 21, 33, 37 and 43 under 35 U.S.C. § 103(a) as obvious in view of U.S. Patent No. 5,749,872 to Kyle et al. ("Kyle") in combination with U.S. Patent No. 5,601,553 to Trebing et al. ("Trebing");
- rejected pending claims 2, 12 and 34 under 35 U.S.C. § 103(a) as obvious in view of Kyle in combination with both Trebing and U.S. Patent No. 4,867,144 to Karas et al. ("Karas");
- rejected pending claims 3, 13 and 35 under 35 U.S.C. § 103(a) as obvious in view of Kyle in combination with both Trebing and U.S. Patent No. 3,630,261 to Gley ("Gley");
- rejected pending claims 4, 6, 14, 16-17, 26, 32, 36 and 38-39 under 35 U.S.C. § 103(a) as obvious in view of Kyle in combination with both Trebing and U.S. Patent Publication No. 2002/0013587 to Winquist et al. ("Winquist");
- rejected pending claims 7, 18 and 40 under 35 U.S.C. § 103(a) as obvious in view of Kyle in combination with both Trebing and U.S. Patent No. 5,674,222 to Berger et al. ("Berger");
- rejected pending claim 22 and 29 under 35 U.S.C. § 103(a) as obvious in view of Trebing in combination with Berger;
- rejected pending claim 23 under 35 U.S.C. § 103(a) as obvious in view of Trebing in combination with both Berger and Karas;
- rejected pending claim 24 under 35 U.S.C. § 103(a) as obvious in view of Trebing in combination with both Berger and Gley;
- rejected pending claims 25 and 27-28 under 35 U.S.C. § 103(a) as obvious in view of
  Trebing in combination with both Berger and Winquist;
- rejected claim 44 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,306,136 to Baccelli ("Baccelli");

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• rejected claims45-46 and 48-49 under 35 U.S.C. § 103(a) as obvious in view of Baccelli in combination with Winquist;

- rejected claim 47 under 35 U.S.C. § 103(a) as obvious in view of Baccelli in combination with both Winquist and Kyle;
- rejected claim 50 under 35 U.S.C. § 103(a) as obvious in view of Baccelli in combination with both Winquist and Berger;
- rejected claim 53 under 35 U.S.C. § 103(a) as obvious in view of Baccelli in combination with both Winquist and Trebing;
- rejected claim 54 under 35 U.S.C. § 103(a) as obvious in view of Baccelli in combination with Karas;
- rejected claim 1, 11 and 22 on grounds of non-statutory obviousness-type double patenting in view of claims 16, 17 and 18, respectively, of U.S. Patent No. 6,623,486 to Weaver et al. ("the Weaver '486 patent"); and
- objected to claims 8-9, 19-20, 30-31, 41-42 and 51-52 as being dependent on a rejected base claim, but otherwise allowable if rewritten in independent form.

Applicants have amended claims 1-2, 8-9, 11-12, 19-20, 22-23, 30-31, 33-34, 41-42, 44, 51-52 and 54 to further define the invention recited, more clearly distinguish over the cited prior art, and/or conform with amendments to other claims. All amendments are fully supported by the originally-filed specification and/or drawings of the present application. No new matter has been added. The claim amendments made herein do not represent acquiescence in the Examiner's rejections, but rather are made only to expedite prosecution of the present application and/or maintain consistency in claim language. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications. As discussed more fully below, Applicants respectfully submit that each of the currently pending claims define features that are not disclosed, taught or suggested by the prior art of record and respectfully requests allowance of same.

# Claim Rejections — 35 U.S.C. §§ 102(e) and 103(a)

Independent claim 44 was rejected under 35 U.S.C. § 102(e) as anticipated by Baccelli. Independent claims 1, 11, and 33 were rejected under 35 U.S.C. § 103(a) as obvious in view of Kyle in combination with Trebing, and independent claim 22 was rejected as obvious in view of Trebing in combination with Berger. Applicants respectfully traverse

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each of these claim rejections and, for the reasons discussed below, submit that none of the cited reference, taken alone or in combination, discloses, teaches or suggests each of the limitations recited in amended independent claims 1, 11, 22, 33 and 44.

## Independent Claim 44

As amended, independent claim 44 recites a bone fixation system comprising, inter alia, a bone plate having at least a first threaded hole passing through the upper and lower surfaces, at least a second non-threaded hole passing through the upper and lower surfaces, a first screw having a shaft with a thread for engaging bone and a non-threaded upper portion for non-locking engagement with the first threaded hole, and a second screw having a shaft with a thread for engaging bone and a head, wherein the first and second screws remain seated in their respective first and second holes for substantially as long as the bone plate is implanted.

Applicants respectfully submit that Baccelli fails to disclose a bone plate with a first threaded hole and a first screw having a shaft with a thread for engaging bone and a non-threaded upper portion for non-locking engagement with the threaded hole. Baccelli also fails to disclose a second non-threaded hole and a second screw having a shaft with a thread for engaging bone, where the second screw is seated in the second non-threaded hole. Baccelli discloses screws 20 having a threaded shank 21 "intended to penetrate cervical vertebrae" and a thread 22 at "the transition between the threaded part 21 and the head 23 . . . intended to cooperate with the thread 1111 provided in the associated opening 111 of the plate element." (Baccelli at col. 2, ll. 44-53.) Thus, Baccelli does not disclose screws having "a non-threaded upper portion for non-locking engagement with the threaded hole" in the bone plate, as recited in amended claim 44. It should also be noted that screws 30 disclosed by Baccelli do not penetrate bone. (Baccelli at col. 3, l. 57 to col. 4, l. 3.)

Accordingly, since Baccelli fails to disclose, teach or suggest all of the elements recited in amended claim 44, applicants respectfully request that the anticipation rejection of claim 44 be withdrawn and that this claim, and each of its dependent claims 45-50 and 53-54, be allowed.

## Independent Claims 1, 11, 22 & 33

Independent claims 1, 11, 22 and 33 have been amended to recite a bone plate comprising, *inter alia*, at least a first threaded hole passing through the upper and lower

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surfaces, at least a second non-threaded hole passing through the upper and lower surface, a first screw having a shaft with a thread for engaging bone and a head with a thread configured and dimensioned to mate with the first threaded hole, and a second screw having a shaft with a thread for engaging bone and a head, wherein the first and second screws remain seated in their respective first and second holes for substantially as long as the bone plate is implanted. These claim amendments make clear that the first screw remains seated in the first threaded hole and the second screw remains seated in the second non-threaded hole for substantially as long as the bone plate is implanted.

Applicants respectfully submit that the combination of Kyle and Trebing fails to disclose, teach or suggest a bone plate as recited in amended claims 1, 11, and 33. Kyle at least fails to disclose a bone plate having a first threaded hole and a first screw having a head with a thread configured and dimensioned to mate with the first threaded hole, as recited in amended claims 1, 11 and 33. Trebing fails to disclose a first threaded hole, a second nonthreaded hole, a first screw having a shaft with a thread for engaging bone and a head with a thread configured and dimensioned to mate with the first threaded hole, and a second screw having a shaft with a thread for engaging bone and a head, wherein the first and second screws remain seated in their respective first and second holes for substantially as long as the bone plate is implanted, as recited in amended claims 1, 11 and 33. As clearly stated in Trebing, non-threaded holes 16, 17 are "for temporary screws to retain the plate in place while permanent screw holes in the bone are precisely located and drilled." (Trebing at col. 1, 11. 55-62; col. 3, 11. 21-23.) Therefore, Trebing fails to disclose, teach or suggest "first and second screws that "remain seated in their respective first and second holes for substantially as long as the bone plate is implanted." See In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (to establish prima facie obviousness, all the claim limitations must be taught or suggested by the prior art).

Moreover, applicants respectfully submit that the rejections of claims 1, 11 and 33 based on the combination of Kyle and Trebing is improper because Trebing actually teaches away from the bone plate recited in those claims by disclosing only temporary screws in the unthreaded holes 16, 17, not screws that remain seated in their respective first and second holes for substantially as long as the bone plate is implanted. See MPEP § 2145. Similarly, Kyle and Trebing also teach away from their combination with one another because the unthreaded holes in Kyle receive permanent lag screws, while the unthreaded holes in Trebing receive only temporary screws. See In re Grasselli, 713 F.2d 731, 743, 218

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USPQ 769, 779 (Fed. Cir. 1983) (improper to combine references where the references teach away from their combination).

Similarly, applicants respectfully submit that the combination of Trebing with Berger fails to disclose, teach or suggest the bone plate recited in amended independent claim 22. Berger at least fails to disclose a bone plate having a first threaded hole and a first screw having a head with a thread configured and dimensioned to mate with the first threaded hole, as recited in amended claim 22. And, as discussed above, Trebing fails to disclose a first threaded hole, a second non-threaded hole, a first screw having a shaft with a thread for engaging bone and a head with a thread configured and dimensioned to mate with the first threaded hole, and a second screw having a shaft with a thread for engaging bone and a head, wherein the first and second screws remain seated in their respective first and second holes for substantially as long as the bone plate is implanted, as recited in amended claim 22. Trebing's non-threaded holes 16, 17 are "for temporary screws to retain the plate in place while permanent screw holes in the bone are precisely located and drilled." (Trebing at col. 1, ll. 55-62; col. 3, ll. 21-23.) These temporary screws are removed before implantation is complete. (Id. at col. 4, ll. 27-31.) Therefore, Trebing fails to disclose, teach or suggest "first and second screws that "remain seated in their respective first and second holes for substantially as long as the bone plate is implanted." See In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (to establish *prima facie* obviousness, all the claim limitations must be taught or suggested by the prior art).

As discussed above, Trebing's disclosure of only temporary screws in holes 16, 17 expressly teaches away from the invention recited in claim 22, which requires that the first and second screws "remain seated in their respective first and second holes for substantially as long as the bone plate is implanted." In addition, Berger and Trebing also teach away from their combination with one another because the unthreaded holes in Berger receive permanent screws, while the unthreaded holes in Trebing receive only temporary screws. See MPEP § 1245.

Accordingly, for the reasons discussed above, applicants respectfully request that the obviousness rejections of claims 1, 11, 22 and 33 be withdrawn and that those claims, and each of their dependent claims 2-7, 10, 23-29, 32, 34-40, and 43, be allowed.

## <u>Claim Rejections — Double Patenting</u>

Claims 1, 11 and 22 were rejected on grounds of non-statutory obviousness-

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type double patenting in view of claims 16, 17 and 18, respectively, of the Weaver '486 patent, which is the parent of the present application. Upon indication that amended claims 1, 11 and 22 are otherwise in condition for allowance, if necessary, applicants will submit a Terminal Disclaimer to obviate any remaining double patenting rejection based on the Weaver '486 patent.

#### Allowable Subject Matter

Applicants would like to thank the Examiner for the indication of allowable subject matter in dependent claims 8-9, 19-20, 30-31, 41-42 and 51-52. Applicants have rewritten each of these claims in independent form, and respectfully request withdrawal of any objections and allowance of new independent claims 8-9, 19-20, 30-31, 41-42 and 51-52.

In view of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider pending claims 1-54 with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

A separate Fee Transmittal Sheet for additional claim fees and a separate petition for a one-month extension of time are submitted herewith. Should any additional fees be required, please charge such fees to Jones Day deposit account no. 50-3013.

Respectfully submitted,

Date: April 26, 2006

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